



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

MARYLOU SUDDERS
Secretary

MONICA BHAREL, MD, MPH
Commissioner

Tel: 617-624-6000
www.mass.gov/dph

September 18, 2015

Alternative Therapies Group, Inc.
Mr. Christopher Edwards
24 R. Pleasant St., Unit 2
Newburyport, MA 01950

Re: Request for an Extension of Temporary Waivers

Dear Mr. Edwards:

On September 5, 2015, Alternative Therapies Group ("ATG") submitted a written request to extend the waiver dated June 19, 2015, as expanded by the waiver request granted on August 31, 2015 (collectively referred to as the "Waiver"), beyond the current waiver expiration date of September 19, 2015. The Waiver waived 105 CMR 725.105(C)(2)(a) as it applies to heavy metals and pesticides, and 105 CMR 725.105(E)(2)(g) and 105 CMR 725.105(E)(3)(i), labeling requirements for finished plant material and cannabis concentrate, subject to the conditions within the Waiver.

In the September 5 extension request, you represented that the single Massachusetts laboratory that currently conducts testing on marijuana products is not "in a position to provide a Cadmium test at the required detection limits," and it is not "able to provide all 18 required pesticide tests at this time." You have submitted testing reports from this laboratory that supports your representation.

I find that compliance would cause undue hardship to ATG and patients, that ATG will institute compensating features acceptable to the Department of Public Health (the "Department") and that with those compensating features, non-compliance does not jeopardize the health or safety of any patient or the public. ATG's September 5, 2015 request for an extension of the Waiver from 105 CMR 725.105(C)(2)(a), only as it applies to heavy metals and pesticides, and 105 CMR 725.105(E)(2)(g) and 105 CMR 725.105(E)(3)(i), labeling requirements for finished plant material and cannabis concentrate, is granted effective as of the day of this letter for an additional three months and will expire on December 19, 2015 (the "Waiver Term"). This extended waiver is subject to the conditions set forth below:

1. For the remainder of the Waiver Term, or until such time that ATG has demonstrated to the Department's satisfaction that it can fully comply with the *Protocol for Sampling and*

Analysis of Environmental Media for Massachusetts Registered Marijuana Dispensaries and Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-Infused Products for Massachusetts Registered Medical Marijuana Dispensaries (collectively, the "Protocols"), whichever occurs earlier, it may only dispense a maximum of 4.23 ounces of finished plant material or the dry weight equivalent of cannabis concentrate (1 gram of cannabis concentrate = 5.16 grams of finished plant material), or a combination of both that would not exceed a total of 4.23 ounces of finished plant material or the dry weight equivalent of cannabis concentrate, and must supply each qualifying patient or caregiver with instructions that for finished plant material, a maximum of 2 grams may be consumed per day, and for cannabis concentrate, a maximum of 1.13 grams be consumed per day;

2. During the Waiver Term, ATG shall continue to conduct testing in compliance with the Protocols for finished plant material and cannabis concentrate for all substances listed in 105 CMR 725.105(C)(2)(a), including heavy metals and pesticides, and submit the results to the Department;
3. During the Waiver Term, ATG shall take all necessary steps to ensure that the presence of heavy metals in finished plant material and cannabis concentrate is as minimal as possible, but shall not be required to meet the levels specified in Exhibit 4 of Section 7 of the *Protocol for Sampling and Analysis of Finished Medical Marijuana and Marijuana-Infused Product for Massachusetts Registered Marijuana Dispensaries*;
4. Consistent with ATG's representation in its request that it does not use the plant-growth regulators and pesticides identified in the Protocol, ATG shall not use any of the plant-growth regulators and pesticides identified in the Protocol during the Waiver Term;
5. During the Waiver Term, ATG shall be subject to increased inspections to ensure compliance with the conditions of this waiver, including requests for additional testing and information regarding the testing capabilities of any independent laboratory selected for testing by ATG;
6. ATG must maintain records available for inspection by the Department that it only dispenses a maximum of 4.23 ounces of finished plant material or the dry weight equivalent of cannabis concentrate (1 gram of cannabis concentrate = 5.16 grams of finished plant material), or a combination of both that would not exceed a total of 4.23 ounces of finished plant material or the dry weight equivalent of cannabis concentrate, and must supply each qualifying patient or caregiver with instructions that for finished plant material, a maximum of 2 grams may be consumed per day, and for cannabis concentrate, a maximum of 1.13 grams be consumed per day;
7. Labels for all marijuana finished plant material and cannabis concentrate produced during the Waiver Term shall disclose that product may not meet the established standards for heavy metals and pesticides:

"WARNING: This product may not meet the established standards for heavy metals and pesticides."

8. The Department reserves the right to revoke or modify this waiver at any time should it determine that ATG, or any of its dispensary agents, fail to comply with the terms and conditions of the waiver, or if the Department finds that the waiver no longer serves the interests of the public health or safety, including in the event that the Department develops updated Protocols pursuant to 105 CMR 725.105(C)(2).

The Department anticipates that ATG will work expeditiously to resolve the issues that have led to the request for an extended waiver. If, however, ATG determines it cannot do so within the extended Waiver Term, a request for any additional waiver must be received by the Department 14 days prior to the expiration of the current waiver. Please contact RMDcompliance@state.ma.us with any questions regarding this waiver.

Sincerely,

A handwritten signature in blue ink, appearing to read 'MBH', is positioned above the printed name of the Commissioner.

Monica Bharel, MD, MPH
Commissioner
Massachusetts Department of Public Health